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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,174	10/15/2003	Jianfu Jeffrey Wang	559312000100	7584

25226 7590 12/15/2004

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,174	WANG ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 9/28/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 29-30 are added to the instant application.
2. Currently, claims 1-30 are under examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 9-11, 12, 14, 16-26 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Belov et al. (Cancer Res. 2001 61: 4483)

Belov et al. teach using antibodies array for immunophenotyping of different leukemia cells. Belov et al. teach immobolized at least 60 antibodies on the microarray, and

subsequent testing the leukocytes from both leukemia patients and normal people on the antibody array (See Method, and Figure 1, page 4484, right column, last paragraph). The antibodies used including CD complement activation molecules family, e.g. CD5, 5, 7, 44, 45, 71, 154, 13, 11....16. The bindings of antibodies-cells and the absence of such bindings reflect the phenotype pattern of the abnormal leukocytes in leukemia patients which is useful for clinical diagnosis (See Figure 1 and Table 1). It is an inherent characteristics that recognizable epitopes for antibodies usually consisting of at least 3, 4 or more consecutive amino acids.

3. Claims 1-30 are rejected under 35 U.S.C. 102 (e) as being unpatentable over Chait et al. (US 2003/0045694)

Chait et al. teach a method of detecting multiple analytes in samples, including controls, by a reporter signals system. Chait et al. teach that immobilzing 3200 antibodies on a micrarray and this inherently encompassing immobilizing less antibodies, such as 100, 200, 300, ...1000 antibodies as recited in claim 5, 29 and 30 (See Section 1306). With respect to claims 13 and 15, Chait et al. also teach pretreatment of the test samples, e.g. digestion or enzymatic cleavage (Section 0043, 0134 and 0137). With respect to claims 14, 17-23, Chait et al. teach washing the unbound samples from the assay (See Section 0205). With respect to claims 17, 19 and 21, Chait et al teach that the test samples can be peptides, proteins, cells, or virus (See Figures 1-3; claims 484, 500 and 509).
Chait et al teach that the collected data of protein binding profiles, e.g. at least two samples, generated by the micrarray are a powerful tool in identifying and characterizing different biological samples (See Sections 0056, 0121, 0126).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belov et al as in view of Chait et al.

The teachings of Belov et al. had been discussed as above, however Belov et al. teach immobilizing 60 antibodies on the microarray instead of 100, 200, 300, 400, 500, 600, 700, 800, 900, 1000 antibodies. Cardone et al. teach a microarray for efficient screening target molecules by immobilizing up to 3200 antibodies on the microarray (See Section 1306). This microarray device also encompasses loading less antibodies, such as 100, 200, 300, ...1000 antibodies depending on circumstances. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Belov et al with more antibodies in a microarray as taught by Chait et al. for mass and efficient screening purposes.

Response to Applicant's Arguments

Belov et al. reference

Applicant argues that the instant invention "claimed digital antibodies recognize very small epitopes, and are expected to bind to multiple proteins in a sample" whereas the Belov et al. reference teaches "an antibody microarray that contains 60 different antibodies that each binds specifically to a particular cell surface marker" (See Remarks, page 10, last paragraph). Applicant further indicates that "specificity of results and information arising from antibody binding is conferred via the binding of sets of digital antibodies to protein in a sample, rather than by binding of a single antibody that binds but one or a few proteins, as commonly used in the art for specific detection" (See Remarks, page 11, first paragraph; Specification Section 0053). Applicant's arguments have been considered but are not persuasive. The distinguishing features outlined by applicant are not recited in the claim language. Belov et al. reference encompasses every element of the recited claims. Thus, the rejection under 35 USC 102(b) is deemed proper.

With respect to the number of consecutive amino acids recognized by the antibody, applicant submits a publication asserting that antibody recognizing 8-12 amino acid, rather than 3-5 amino acids as recited in the instant claims are commonly used in the art. Therefore, inherency rejection is not supported in the field. Applicant's argument has been considered but is not persuasive. Belov et al. reference teaches using at least 60 various antibodies for microarray analysis. It is inherent characteristic for some antibodies recognizing 3-5 shorter polypeptides instead of longer 8-12 polypeptides, as evidence by Northrop et al. (US 6410245). Northrop et al. review that epitopes can be at least about 3 consecutive amino acids long (See Col. 15, line 45-50). Accordingly, in general, epitopes for antibody is at least about 3 amino acids as recited in the claim language.

Chait et al. reference

Applicant's main argument is that Chait et al. do not teach using antibodies that bind small epitopes of 3-5 amino acids as presently claimed. Furthermore, applicant indicates that "in the present specification, antibodies that bind small epitopes as claimed are expected to each bind to a number of proteins in a sample, i.e., they are cross-reactive with multiple proteins" (See Remarks, page 12, third paragraph). Applicant's argument has been considered but is not persuasive. Examiner had indicated in this Office Action that there is no positively recitation of this feature. Additionally, as discussed above that the epitopes recognized by antibodies can be of at least 3 consecutive amino acids. Accordingly, Chait et al. reference anticipates the instant claims.

Conclusion

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

December 3, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/10/04